REMARKS

Claims 38 and 39, which were withdrawn from consideration by the Examiner, have been canceled without prejudice to continued prosecution. Claim 7 has been amended to recite that the cells can be stem cells. Support for this amendment can be found, for example, at page 8, lines 6-8 and line 16. No new matter has been added. Applicants respectfully request reconsideration and allowance of claims 1-37 in view of the following remarks.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 1-37 under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner asserted that "[t]he specification fails to support that the disclosed results can be obtained with a device without structure as required by claims 1, 3 and 5 in combination." Applicants respectfully traverse.

The specification enables one of ordinary skill in the art to make and use the claimed invention. In particular, the specification provides a number of materials that can be used to produce non-woven frameworks. For example, the specification indicates at page 4, line 28 through page 5, line 2 that the non-woven framework can be composed of metal fibers such as stainless steel, tantalum, titanium, gold, platinum, or silver, alloys of such metals (e.g., shape-memory alloys of nickel-titanium such as Nitinol), as well as any other biocompatible metals. The specification also indicates that non-woven frameworks can be composed of inert polymers, including, for example, polyethylene terephthalate, polytetrafluorethylene, and bioresorbable polymers such as polylactic acid, polyglycolic acid, or poly (N-acetyl-D-glucosamine). See, for example, the specification at page 5, lines 15-18.

The specification provides methods that can be used to form non-woven frameworks from metal or polymer fibers. For example, the specification indicates, at page 4, lines 27-29, that metal fibers can be formed into a non-woven framework by pressing the metal fibers on a flat surface then heating (e.g., sintering) so the fibers fuse wherever they are in contact with one another. The specification also indicates that spunbound or melt blown processes can be used to produce non-woven frameworks from inert polymers. See, for example, the specification at page 5, lines 5-6.

The specification provides methods for fabricating implantable medical devices from non-woven frameworks. For example, the specification indicates that metal non-woven frameworks can be cut, for example, by lasers, electro-discharge machining, or plasma cutting. Welding techniques such as electron beam welding, gas tungsten arc welding, plasma welding, spot welding, laser welding, and ultrasonic welding can be used to bond metal non-woven frameworks. See, for example, the specification at page 6, lines 26-30. The specification also provides methods for attaching non-woven frameworks to at least a portion of at least one surface of an implantable medical device, including coating, welding, and adhesion techniques. See for example, the specification at page 7, lines 15-22.

The Examiner asserted that the "claimed invention must be commensurate in scope with the working examples carried out." Applicants respectfully disagree.

The standard test for enablement is whether the disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention without undue experimentation. See, MPEP §2164.01. Compliance with the enablement requirement does not turn on whether an example is disclosed. See, MPEP §2164.02. Furthermore, as indicated in §2164.02 of the MPEP, "representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation."

One of ordinary skill in the art would be able to make and use the non-woven frameworks and implantable medical devices of claims 1-37. As indicated above, the specification provides methods and materials for making non-woven frameworks, and methods and materials for producing implantable medical devices from the non-woven frameworks. The specification further provides working examples that indicate non-woven frameworks provide a three-dimensional structure that is suitable for cell growth. The non-woven framework allows close cell-cell contact, which may increase paracrine and autocrine growth factor enrichment and ensure more rapid cell colonization of the framework. See, for example, the specification at page 5, lines 21-24. While coating the non-woven framework with an extracellular matrix protein significantly increased cell seeding and cell retention, uncoated non-woven frameworks still

provided a three-dimensional structure for cell growth. See, page 14, lines 3-6 of the specification. Thus, the specification, as filed, contains sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention without undue experimentation. In view of the above remarks, the Examiner is requested to withdraw the rejection under 35 U.S.C. §112, first paragraph.

CONCLUSION

Attached is a marked-up version of the changes being made by the current amendment.

Applicants ask that claims 1-37 be allowed. No fees are due as this response is being filed before the end of the shortened statutory period. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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Version with markings to show changes made

In the claims:

Claims 38 and 39 have been cancelled.

Please amend claim 7 as follows:

7. (Amended) The implantable medical device of claim 5, wherein said non-woven framework further comprises cells selected from the group consisting of smooth muscle cells, stem cells, fibroblasts, hepatocytes, and endothelial cells.